K121983

PREMARKET NOTIFICATION [510(k)] Summary

SEP 7 2012

Company Name: BenQ Medical Technology Corporation
7F., No. 46, Zhou-Z St., Nei-Hu, Taipei 114, Taiwan

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Device Name: UP600 Diagnostic Doppler Ultrasound System with
C52 Curved Linear Array 2-5MHz,
L115 Linear Array 5-11MHz,
P42 Phase Array 80 elements 2-4MHz.

Common Name: Diagnostic Ultrasound Imaging System

Classification Name: Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Diagnostic Ultrasound Transducer 21 CFR *892.1570,* Product Code 90-ITX

Registration Number: 3003574554

Factory Location: Qisda Corporation
159 Shan-ying Road, Gueishan,
Taoyuan 333, Taiwan

Reason for Submission:
This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

Predicate Device Comparison:
The GE Voluson i (K053435) is of a comparable and substantially equivalent type. It has the same technological characteristics, key safety and effectiveness features, physical design, and has the same intended uses and basic operating modes as the predicate device.

General Device Description:
The UP600 diagnostic doppler ultrasound system is a compact and portable diagnostic

ultrasound device, have integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The user interface includes a specialized control keyboard and color 15-inch LCD display. The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

The major features of the UP600:

- 128 Channel all digital beam former
- Progressive dynamic receive focusing
- Wide band all digital demodulation
- Native resolution digital scan converter
- Hand carried for portable use
- Remote access image management through LAN port
- USB2.0 flash drive for image transport and software upgrade
- Supports 2D B-mode, M-mode, Harmonic Image, Color, Power Doppler, Pulse wave Doppler, and CW.

Intended Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), heart soft tissue, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, Ob/Gyn.

Technological Characteristics:

Display Modes	Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time.
Measurements	Distance; area; circumference; calipers; velocity, PI, RI. OB, Urology, Cardiac and Vascular package.
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, and Doppler spectrum image for diagnostic purpose.

Operating Controls	• Low noise TGC: 8 slider settings • Depth Range: 3 to 24 cm • Image sector size: 32 lines to full B (256 lines) • Image Sector position: Steering within full maximum • B orientation flip: L/R key with marking on the screen • B Dynamic range control: preset 14 curve settings • Gray Scale Control: 7 Settings • Focal Number: up to 12 focal zone settings • B persistence: 30-90% 7 settings • Image Processing: Smoothing, edge enhancement • PW sweeping speed 2,4,6,8 sec over display. • PW Wall filter setting: 16 settings, 0.25 to 20% of PRF • PW sample volume: 1 to 20mm with 0.5mm step size. • PW/B update: with UPDATE key • PW cursor steering: Steer soft key • PW angle correction: 0 to 70 degree user control • PW trace: Peak, Mean • PW spectrum dynamic range: 5 preset curve settings • Spectrum baseline shift and invert • Color ROI setting: trackball and set key to control size and position • Color steering on flat probe: +, 0, - • Color Wall Filter: Color wall filter with 16 selection, 0.25-20% • Color Packet size: preset per Probe and Exam • Zoom factor: 1 to 10 continuously • Freeze control: Toggling freeze key • Cine control: step, play backward, play continuously
Acoustic Output	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC: 0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm 2max

SAFETY CONSIDERATIONS:

UP600 has been designed to meet the following voluntary and measurement standards:

- EC 60601-1 Safety of Medical Electric Equipment
- AIUM/NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)

Safety and EMC Requirements for Medical Equipment

- EN 60601-1
- EN 60601-1-2
- EN 60601-2-37
- ISO 10993 Biocompatibility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 7 2012

BenQ Medical Technology Corporation
% Mr. Bob Leiker
Owner/Manager
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
DUBLIN CA 94568

Re: K121983
Trade/Device Name: UP600 Diagnostic Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory: II
Product Code: IYN, IYO, ITX
Dated: August 4, 2012
Received: August 7, 2012

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the UP600 Diagnostic Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

C52 Curved Linear Array 2-5MHz
L115 Linear Array 5-11MHz
P42 Phase Array 80 elements 2-4MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Gary Levine at (301) 796-6934.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Tab 3 Indications For Use

To

510(k) Number (if known):

Device Name: **UP600 Diagnostic Doppler Ultrasound System**

Indications for Use: The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), heart soft tissue, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, Ob/Gyn.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
510k K121983

Diagnostic Ultrasound Indications for Use Form

System: **UP600 Diagnostic Doppler Ultrasound System**
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N
	Abdominal	N	N	N		N	N	Note 1	N
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	N
	Small Organ (breast, thyroid, testes)	N	N	N		N	N	Note 1	N
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	N
	Adult Cephalic	N	N	N	N	N	N	Note 1	N
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N
	Other (specify)								

N = new indication; **P = previously cleared by FDA** **E = added under this appendix**

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Diagnostic Ultrasound Indications for Use Form

Transducer: C52 Curved Linear Array 2-5MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	N
	Abdominal	N	N	N		N	N	Note 1	N
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

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Diagnostic Ultrasound Indications for Use Form

Transducer: L115 Linear Array 5-11MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)	N	N	N		N	N	Note 1	N
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	N
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	N
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	N
	Other (specify)								

N = new indication; **P = previously cleared by FDA;** **E = added under this appendix**

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

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Diagnostic Ultrasound Indications for Use Form

Transducer: P42 Phase Array 80 elements 2-4MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Tissue Harmonic Imaging**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	Note 1	N
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	N
	Adult Cephalic	N	N	N	N	N	N	Note 1	N
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	N
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	N
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; **P = previously cleared by FDA;** **E = added under this appendix**

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

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